Written Testimony of Campaign for Tobacco-Free Kids

In Support of SB 367:

AN ACT CONCERNING ELECTRONIC NICOTINE DELIVERY SYSTEMS AND VAPOR PRODUCTS

Joint Committee on Public Health

Hartford, Connecticut
March 13, 2022

The Campaign for Tobacco-Free Kids submits these written comments in support of SB 367, proposed legislation to prohibit the sale of electronic nicotine delivery systems and vapor products that are flavored or that have a nicotine content that is greater than thirty-five milligrams per milliliter in Connecticut. The Campaign for Tobacco-Free Kids is the nation's largest non-profit, non-governmental advocacy organization solely devoted to reducing tobacco use and its deadly toll by advocating for public policies that prevent kids from using tobacco, help smokers quit and protect everyone from secondhand smoke.

For decades, the tobacco industry has been using flavored products to hook kids into a lifetime of addiction. First with menthol cigarettes, then with flavored chew and cigars, and now most recently with a bewildering variety of flavored e-cigarettes. Over 15,000 flavors[1] have been introduced to the marketplace in the last 10 years and the impact on youth addiction has been both clear and devastating.

Flavors hook kids by improving the taste and reducing the harshness of tobacco products, making them more appealing and easier for beginners to try the product and ultimately become addicted. Menthol is especially effective at doing this, as it cools and numbs the throat, reducing the harshness of cigarette smoke. Although it has been used historically in combustible cigarettes, cigars and smokeless tobacco products; menthol is now one of the most popular e-cigarette flavors as well as being the cigarette that 41% of high school smokers use.[2]

95% of all tobacco users start their addictions before they turn 21,[3] and 80% of kids who have ever used tobacco started with a flavored product.[4] Research has proven that the two factors that are most likely to determine whether kids get addicted to tobacco are price and the availability of flavors. If tobacco is cheap, and flavors are available, kids are more likely to start smoking or vaping. The continued availability of flavored tobacco products puts all of our kids at risk. Passage of SB 367 is the best way for Connecticut to finally end the cycle of addiction that the tobacco industry, and their flavored tobacco products, have perpetrated for far too long.

E-cigarette Use by Youth Remains A Serious Public Health Concern

Make no mistake – the e-cigarette epidemic is an epidemic of historic proportions and its devastating impact on Connecticut's youth is the direct result of deliberate decisions made by tobacco companies/e-cigarette companies to follow the same path tobacco companies have always followed - maximize sales and profits without regard to the consequences or the impact on our citizens and youth.

When e-cigarettes were introduced, the e-cigarette industry claimed the target was adult smokers who could not quit. The reality has been entirely the opposite. E-cigarettes have been marketed in over 15,000 flavors that have fueled use by our kids.[5] They are sold in devices that deliver potent doses of nicotine in a manner that masks its risks and leads to rapid, intense addiction. They are packaged as sleek, high-tech devices that youth who would never consider smoking perceive as cool and risk free and that enable youth to use without being discovered by parents or teachers.

And they are marketed on social media websites popular with youth using images identical to those used by the cigarette industry to attract generations of kids.

In 2021, during the midst of the Covid-19 pandemic, over 2 million youth, including 11.3% of US high schoolers, were current e-cigarette users. While the data are not comparable to previous survey years due to methodology changes[1], just prior to the pandemic in 2020, 19.6% of US high schoolers reported current e-cigarette use, about the same level as in 2018 when the Surgeon General first declared e-cigarette use an epidemic."[6]

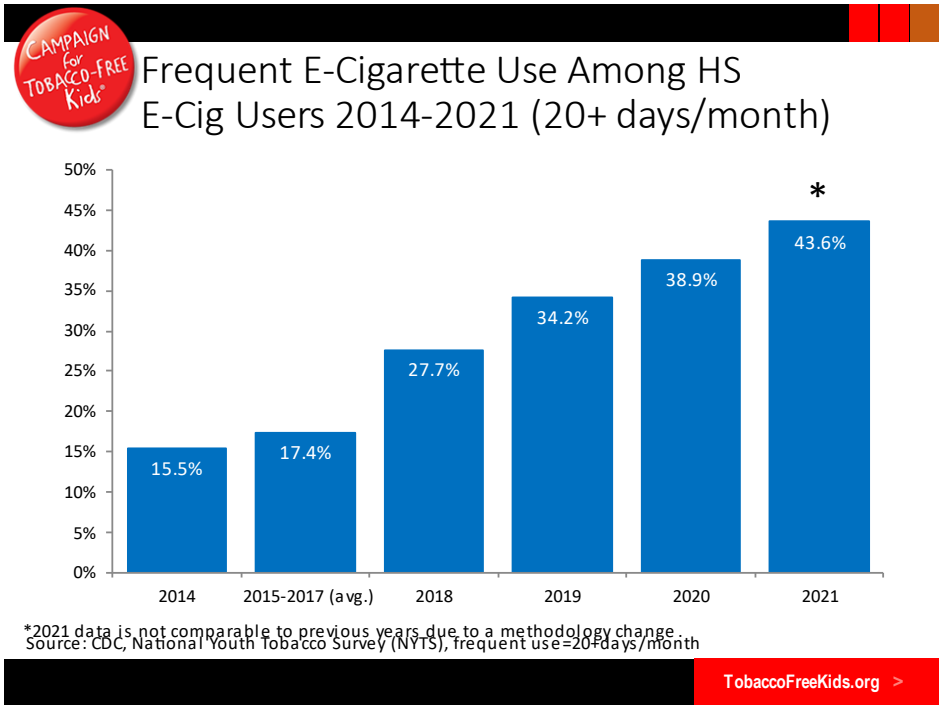
We are at a critical juncture in our nation's public health history. After making tremendous progress in reducing youth tobacco use over the past several decades, e-cigarettes are undermining this progress. Despite declines in youth e-cigarette use since its peak in 2019—when a startling 27.5% of US high schoolers were e-cigarette users—youth e-cigarette use remains a serious public health concern. History shows how rapidly these trends can change. For example, the University of Michigan's national Monitoring the Future Study found that the increase in youth vaping of nicotine from 2017 to 2018 was the single largest one-year increase in youth use *of any substance* in the survey's 43-year history.[7] With students now back in school, we face the real risk of a resurgence in youth tobacco use, especially e-cigarette use, unless policymakers take action to eliminate the flavored products that are driving youth use.

Here in Connecticut, the latest data from the 2019 Youth Risk Behavior Survey show that one in four (27%) of high schoolers are current e-cigarette users.[8] There is no doubt that e-cigarettes are reversing decades of progress that Connecticut has made in reducing youth tobacco use and are addicting a new generation of kids.

Youth E-Cigarette Users Struggle with Addiction

Even more alarming is that an increasing number of youth e-cigarette users are not just experimenting, but are using these products frequently, with many youth becoming rapidly and seriously addicted. The proportion of youth who are using e-cigarettes frequently has steadily increased over the past several years (see chart below). In 2021, 43.6% of high school e-cigarette users were frequent users of e-cigarettes, reporting use on at least 20 of the preceding 30 days. Alarmingly, 27.6% of high school users were daily users, a strong indication of addiction. In total, over 800,000 middle and high school students were frequent users of e-cigarettes in 2021, including half a million daily users.[9]

[1] 2021 data is not comparable to previous years due to a methodology change. Whereas previous surveys were conducted entirely in-school, the 2021 survey included both in-school and at-home responses; students who completed surveys in school reported higher e-cigarette use. Pandemic-related factors such as reduced access to e-cigarettes due to fewer peer interactions may have impacted youth e-cigarette use in 2021.



Data from another study, the International Tobacco Control Policy Evaluation Project (ITC) Youth Tobacco and Vaping Survey, found that between 2017 and 2019, the proportion of current youth e-cigarette users reporting strong urges to use e-cigarettes on most days or more often increased. In 2019, 53.1% of youth e-cigarette users reported they were either 'a little' or 'very addicted' to e-cigarettes.[10] The survey also found that youth who use higher nicotine concentrations report more intensive vaping behavior, including the number of days vaped in the past 30 days, the number of times vaping in an average day of use, the number of days ever vaped, experiencing frequent strong urges to vape and feeling 'a little' or 'very addicted' to vaping.[11]

These statistics are confirmed by the actual experience of parents and pediatricians across the country. Prior to the closure of schools due to COVID-19, e- cigarette use had permeated schools and the daily life of American youth. It is clear that large numbers of teen e-cigarette users are struggling with nicotine addiction and withdrawal. The New York Times profiled Matt Murphy from Reading, MA who had his first Juul when he was 17. He described the euphoric head rush of nicotine as "love at first puff". He became so dependent on Juul that he nicknamed the device his "11th finger."[12] He is not alone. The problem is so bad that FDA convened a public hearing to gather input on how to help youth addicted to the nicotine in e-cigarettes. No one is quite sure how to help these youth quit. There is no question, though, that prohibiting the sale of flavored e-cigarettes will help prevent kids from ever getting hooked.

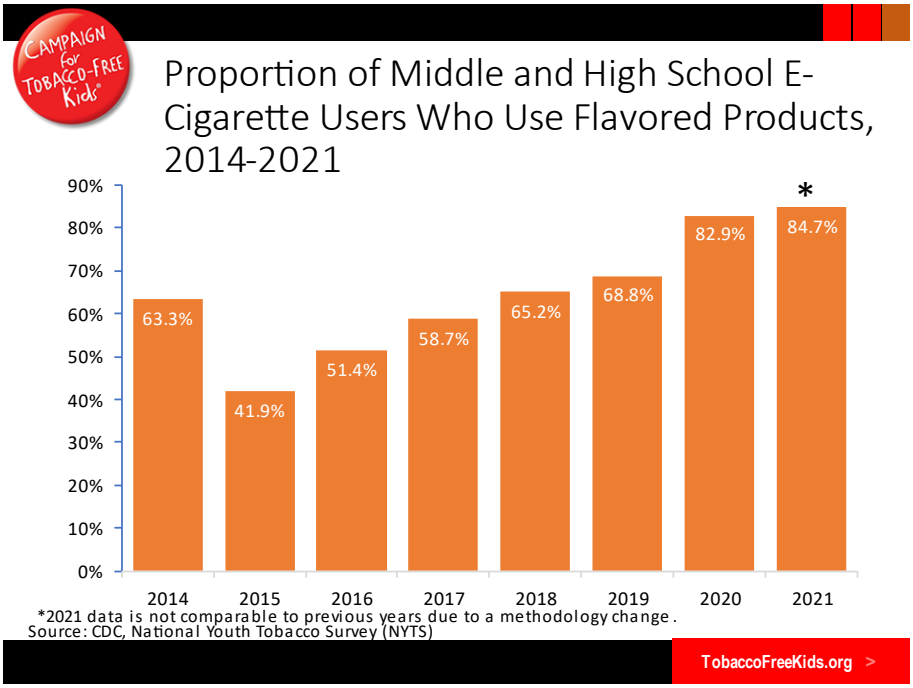
Flavored E-Cigarettes Have Fueled the Popularity of These Products Among Kids

The evidence is clear that flavored e-cigarettes, like mint, mango and gummy bear, have fueled this epidemic. In recent years, there has been an explosion of sweet-flavored e-cigarettes. As of 2017, there were more than 15,500 unique e-cigarette flavors available online, including many kid-friendly flavors like gummy bear, cotton candy, and peanut butter cup.[13] Research shows that flavored products are not only popular among youth, but play a role in initiation and uptake of tobacco products. As the 2020 Surgeon General Report on Smoking Cessation succinctly stated, "the role of flavors in promoting initiation of tobacco product use among youth is well established."[14] An earlier Surgeon General Report on e-cigarettes concluded that flavors are among the most commonly cited reasons for using e-cigarettes among youth and young adults.[15] The FDA has also concluded that, "The published literature is sufficient to demonstrate the substantial appeal to youth of flavored ENDS [e-cigarettes], because it is robust and consistent… the preference for use of flavored ENDS among youth is consistently demonstrated across large, national surveys and longitudinal cohort studies."[16] The most recent data show that flavors continue to drive youth use:

- The 2021 NYTS found that about 85% of youth e-cigarette users use flavored products, a proportion that has only grown in recent years (see graph below). Among high school students who currently used any type of flavored e-cigarette, the most commonly used flavor types were fruit (72.3), candy/desserts/other sweets (33%), mint (30.5%) and menthol (29.8%).[17]

- Earlier data from the 2016-2017 wave of the FDA's Population Assessment of Tobacco and Health study found that 97% of current youth e-cigarette users had used a flavored e-cigarette in the past month and 70.3% say they use e-cigarettes "because they come in flavors I like."[18]

- While flavors other than tobacco and menthol are now prohibited in cartridge-based e-cigarettes, disposable e-cigarettes come in a wide array of kid-friendly flavors, like cotton candy, strawberry, and mint, which have become increasingly popular among kids. In 2021, 55.8% of high school e-cigarette users reported using disposable e-cigarettes.[19] Among current youth users of disposable e-cigarettes, the most commonly used flavor types is fruit (78.7%), followed by candy/desserts/other sweets (32.3%).[20]



If anything, these official government figures underreport the percentage of youth who use flavored e-cigarettes. Any teacher, school principal or high school student will tell you that virtually every kid who uses an e-cigarette, uses a flavored e-cigarette. It is the reason that banning flavored e-cigarettes is an essential step in reversing the youth e-cigarette epidemic. Anything less will fail.

E-cigarettes didn't become popular with kids by accident. E-cigarette makers have introduced products with thousands of flavors that appeal to young people and engaged in the kind of marketing that mirrors what the cigarette industry did for decades. The 2016 Surgeon General Report on e-cigarettes concluded that, "E-cigarettes are marketed by promoting flavors and using a wide variety of media channels and approaches that have been used in the past for marketing conventional tobacco products to youth and young adults."[21]

The use of flavors in e-cigarette products is of even greater concern because e-cigarettes are the subject of extensive advertising campaigns, and there is evidence that young people are exposed to significant amounts of e-cigarette advertising. By mimicking the tobacco industry's strategies, including celebrity endorsements, slick TV and magazine advertisements, and sports and music sponsorships, e-cigarette advertising has effectively reached youth and young adults. The 2021 NYTS found that 7 out of 10 middle and high school students—17.77 million youth—report being exposed to e-cigarette advertisements.[22]

Nicotine Use Has Serious Health Consequences for Youth

Though there is insufficient research on the long-term effects of using e-cigarettes in general, there is a growing body of evidence of immediate harms, many of which are caused by the intense addiction caused by the high levels of nicotine these products deliver. Nicotine is a highly addictive drug and

young people are especially vulnerable to nicotine addiction. Nicotine can have lasting damaging effects on adolescent brain development, because brain development continues until about age 25. According to the Surgeon General, "because the adolescent brain is still developing, nicotine use during this critical period can disrupt the formation of brain circuits that control attention, learning, and susceptibility to addiction."[23] Nicotine can also prime the brain for addiction to other drugs.[24] Because of these risks, the Surgeon General found that, "The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe."[25]

The observable immediate harms from e-cigarette use have increased since the introduction of Juul and Juul-like products. Since the introduction of Juul, youth are now using products that effectively deliver very large doses of nicotine. Juul pioneered a new e-liquid formulation that delivers nicotine more effectively and with less irritation than earlier e-cigarette models. According to the company, the nicotine in Juul is made from "nicotine salts found in leaf tobacco, rather than free-base nicotine," in order to "accommodate cigarette-like strength nicotine levels."[26] A 2018 Surgeon General advisory on e-cigarette use among youth warned that nicotine salts allow users to inhale high levels of nicotine more easily and with less irritation than e-cigarettes that use free-base nicotine. As a result, it is easier for young people to initiate the use of nicotine with these products.[27] A single Juul pod can deliver as much nicotine as a pack of cigarettes.[28] One study estimated that youth could meet the threshold for nicotine addiction by consuming just one quarter of a Juul pod per day.[29] The 2021 National Youth Tobacco Survey (NYTS) found that among high school e-cigarette users, the most commonly reported reason for using e-cigarettes was "to get a high or buzz from the nicotine," reported by 45.3% of users.[30] Similarly, a survey of Connecticut high school students found that 52% of high school Juul users reported liking Juul because it gives them a "buzz."[31]

Juul's competitors, seeking to emulate the company's success, have since flooded the U.S. market with similar pod-based e-cigarettes, including some that have nicotine levels even higher than Juul's, resulting in what some researchers have referred to as a "nicotine arms race." Many of these companies offer the devices and pods that are cheaper than Juul and in a wider variety of kid-friendly flavors.[32] An analysis of e-cigarette sales in Nielsen-tracked channels[†] found that products with 5% nicotine or higher increased from 0% of dollar sales in 2013 to 31.8% in 2017, and then doubled to 66.4% in 2018. In 2018, fruit-flavored e-liquids had a higher mean nicotine concentration (4.7%) than any other flavor category.[33]

Youth E-Cigarette Users Are at Increased Risk of Smoking Cigarettes

E-cigarettes are addicting a new generation of kids and threaten to reverse decades of progress in reducing youth tobacco use. Alarmingly, evidence also continues to build that for young people, using e-cigarettes increases the likelihood of smoking cigarettes.

- In 2016, the Surgeon General concluded that while more research is needed, evidence from several longitudinal studies suggests that e-cigarette use is "strongly associated" with the use of other tobacco products among youth and young adults, including conventional cigarettes.[34]

[†] Tracked data includes mass channel and convenience stores; does not include online sales or sales from tobacco and vape shops.

- In 2018, the National Academies of Science, Engineering & Medicine (NASEM) released a comprehensive report which found that there was substantial evidence that that e-cigarette use increases risk of ever using cigarettes among youth and young adults. The NASEM report also concluded, "There is moderate evidence that e-cigarette use increases the frequency of subsequent combustible tobacco cigarette use" among youth and young adults.[35]
- An analysis of data from the FDA's nationally representative Population Assessment of Tobacco and Health (PATH) study found that from 2013 to 2016, youth (ages 12-15) e-cigarette use was associated with more than four times the odds of trying cigarettes and nearly three times the odds of current cigarette use. The researchers estimate that this translates to over 43,000 current youth cigarette smokers who might not have become smokers without e-cigarettes.[36]
- The World Health Organization's 2021 Report on the Global Tobacco Epidemic concluded that "ENDS use among children and adolescents increases the chances they will use conventional cigarettes and other tobacco products"[37] based on findings from a systematic review and meta-analysis of 25 studies published through 2020, which found that youth who had used e-cigarettes had three times the risk of ever trying cigarettes and more than two times the risk of current smoking.[38]

Multiple studies have also demonstrated that many youth who use e-cigarettes are kids who are among those least at risk of cigarette smoking. For these kids, e-cigarettes are not replacing cigarettes, they are turning non-tobacco users into tobacco users.[39] The FDA also recently noted that, the evidence that e-cigarette use is associated with smoking uptake "increases concern that over time—and particularly if youth ENDS use were to return to the rates seen in 2019 or worsen—the trend of declining cigarette smoking could slow or even reverse."[40]

E-Cigarettes Can Expose Users to Harmful Chemicals

E-cigarettes can also expose users to other harmful chemicals. Studies have found that e-cigarettes can contain harmful and potentially harmful chemicals, including formaldehyde, acrolein, volatile organic compounds, and metals like nickel and lead.[41] More research is needed about the chemicals found in e-cigarettes and the impact of inhaling these chemicals deeply into the lungs.[42]

Flavored e-cigarettes may pose unique harms. According to the Surgeon General, "while some of the flavorings used in e-cigarettes are generally recognized as safe for ingestion as food, the health effects of their inhalation are generally unknown" and noted that some of the flavorings found in e-cigarettes have been shown to cause serious lung disease when inhaled.[43] An article in the *Journal of the American Medical Association* raised concerns that the chemical flavorings found in some e-cigarettes and e-liquids could cause respiratory damage when the e-cigarette aerosol is inhaled deeply into the lungs.[44] According to the FDA, "Flavorings that are safe for use in food may become toxic when these chemicals are heated and inhaled. Some have been shown to be harmful to the lungs."[45]

In *Nicopure Labs LLC v. FDA,* a federal appellate court recognized that "[e]-cigarettes are indisputably highly addictive and pose health risks, especially to youth, that are not well understood."[46] Furthermore, the court noted that "[e]-cigarette liquids and vapor contain chemicals in addition to

nicotine that pose known risks. The aerosol emitted from e-cigarettes is not simply water vapor; rather e-cigarette aerosols have been found to contain at least carbonyls, tobacco specific nitrosamines, heavy metals, and volatile organic compounds. E-liquids may contain formaldehyde, diacetyl, acetyl propionyl and various aldehydes. Aldehydes, 'a class of chemicals that can cause respiratory irritation' and 'airway constriction,' appear in many flavored e-cigarettes, including cotton candy and bubble gum. One study found that the flavors 'dark chocolate' and 'wild cherry' exposed e-cigarette users to more than twice the recommended workplace safety limit for two different aldehydes. Like secondary smoke inhalation from conventional cigarettes, exhaled aerosol from e-cigarettes may include nicotine and other toxicants that can pose risks for non-users."[47]

Despite the known and unknown risks of e-cigarettes, has been slow to act on its review of e-cigarette products.[48] Thus, users and non-users of e-cigarettes continue to be exposed to harmful chemicals in e-cigarettes, with risks that are not yet fully understood.

Long-term Health Effects of E-Cigarettes are Unknown

Little is known about the long-term effects of e-cigarette use. In a 2020 report, the Surgeon General found that "the long-term health effects of using these products remain unknown, and short-term risks are only slowly coming into focus."[49] There are thousands of e-cigarette devices and liquids on the market without any FDA review of what they are delivering into people's bodies and their long-term health risks.

Recently, the WHO Global Tobacco Control Report detailed the emerging evidence of the harmful effects of e-cigarettes, including studies suggesting that e-cigarettes have negative effects on aspects of cardiovascular and respiratory health.[50] The 2020 Surgeon General's report also noted that, "Several studies demonstrate e-cigarette aerosol contains fine and ultrafine particles, such that use of the products could potentially increase cardiovascular and respiratory risks."[51]

- E-cigarettes have been found to increase heart rate and blood pressure, and initial research indicates that the aerosol can damage DNA and the respiratory system. But because the products are relatively new, there is not enough information to assess the long-term impact on cancer, respiratory disease, and heart disease risk.[52]

- There is growing evidence that vaping can harm lung health. In a 2019 review of the evidence on the effects of e-cigarettes on respiratory health, researchers found that, "Studies show measurable adverse biologic effects on organ and cellular health in humans, in animals, and in vitro." E-cigarette aerosol inhibits several kinds of immune cells in the lungs, compromising the ability to fight infection,[53] and initial evidence indicates that e-cigarette aerosol promotes inflammation in the respiratory system.[54] Researchers also noted that, "The effects of e-cigarettes have similarities to and important differences from those of cigarettes. Decades of chronic smoking are needed for development of lung diseases such as lung cancer or chronic obstructive pulmonary disease, so the population effects of e-cigarette use may not be apparent until the middle of this century. We conclude that current knowledge of these effects is insufficient to determine whether the respiratory health effects of e-cigarette are less than those of combustible tobacco products."[55]

The Claim that E-Cigarettes are 95% Safer than Cigarettes is Erroneous and is Widely Disputed by Researchers

Claims that e-cigarettes are 95% safer than cigarettes, popularized by an estimate in a 2015 Public Health England (PHE) report are unfounded. Significantly, not a single U.S. health authority or government agency has supported this claim. In fact, the claim is widely disputed by U.S. government agencies and medical associations.

- The FDA has noted that the panelists conducting the underlying harm analysis "were selected without any formal criterion," that there was a "lack of hard evidence" supporting most of the harm analysis, and that the methodology for arriving at the relative harm assessments underlying the "95% safer" conclusion was "unclear." [56]

- A 2020 article in the American Journal of Public Health concluded, "The "95% safer" estimate is a "factoid": unreliable information repeated so often that it becomes accepted as fact." This article also notes "the evidence-lacking estimate derived in 2013 cannot be valid today and should not be relied upon further." Since 2013, a substantial amount of new evidence has emerged about e-cigarettes. The article notes that the devices are now more powerful, create more aerosol, and expose users to more toxicants. The proliferation of e-liquids with nicotine salts allow users to inhale significantly higher levels of nicotine. More research has emerged about the toxicants in e-cigarettes, and their potential respiratory and cardiovascular effects.[57]

- An editorial in *The Lancet* concluded that, "the opinions of a small group of individuals with no pre-specified expertise in tobacco control were based on an almost total absence of evidence of harm. It is on this extraordinarily flimsy foundation that PHE based the major conclusion and message of its report."[58]

Studies continue to raise new concerns about e-cigarettes and the evidence is insufficient to reach definitive conclusions regarding their relative health risk compared to cigarettes. The 2018 NASEM report found that a great deal of scientific uncertainty still exists regarding the relative safety of e-cigarettes and that, "the absolute risks of the products [e-cigarettes] cannot be unambiguously determined at this time. Long-term health effects, of particular concern for youth who become dependent on them, are not yet clear."[59]

E-Cigarettes Have Not Been Proven to Help Smokers Quit

No major scientific body in the United States has concluded that e-cigarettes are an effective tobacco cessation device. Leading public health authorities in the U.S. have found that there is not enough evidence to recommend e-cigarettes for tobacco cessation, and no e-cigarette has received approval from the FDA to be sold as a tobacco cessation product:

- The 2020 Surgeon General Report on Smoking Cessation concluded that "there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation." The Surgeon General also cautions that because e-cigarettes are not a single product, but "a continually changing and heterogeneous group of products" that "are used in a variety of

ways," it is difficult to make broad generalizations about the efficacy of e-cigarettes for smoking cessation based upon any one study or any one product.[60]

- The U.S. Preventive Services Task Force, which makes recommendations about the effectiveness of specific preventive care services after a thorough assessment of the science, concluded that "the current evidence is insufficient to recommend electronic nicotine delivery systems for tobacco cessation…."[61]
- A 2018 NASEM report concluded, "[o]verall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation." [62]
- Researchers from the CDC stated, "There is currently no conclusive scientific evidence that e-cigarettes promote long-term cessation, and e-cigarettes are not included as a recommended smoking cessation method by the U.S. Public Health Service." [63]
- The World Health Organization (WHO) reported in their 2021 Report on the Global Tobacco Epidemic that, "evidence on the use of ENDS as a cessation aid is inconclusive".[64] The report notes the limitations with the evidence that suggests that e-cigarettes can help smokers quit: the certainty of evidence is low to moderate and the products evaluated do not reflect the current landscape of e-cigarette products available.
- In a court brief from 2019, the FDA stated that, "the claim that vaping helps smokers quit in meaningful numbers remains unproven."[65] FDA is the federal agency charged with determining what products are effective at helping smokers quit.

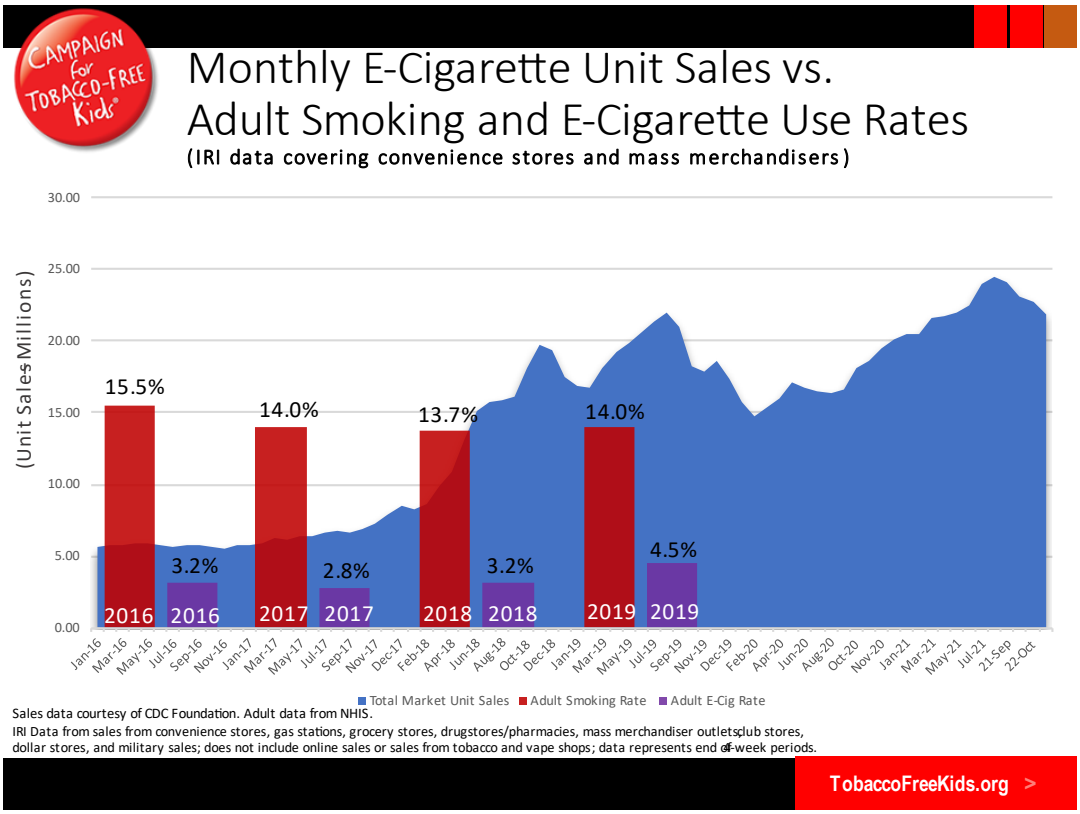
Additionally, several recent studies have found that e-cigarette use is not associated with successful quitting.

- A 2022 study published in *Tobacco Control,* analyzing data from FDA's Population Assessment of Tobacco and Health (PATH) survey, found that recent former smokers who had used e-cigarettes to quit had a significantly lower rate of staying quit from cigarette smoking compared to those who had quit used either no e-cigarette products or specifically used any NRT/pharmaceutical aid. [66]
- Another study also analyzing FDA's PATH survey Waves 3 and 4 (2015-2016; 2016-2017) found that there were no significant differences between rates of successful smoking cessation for electronic nicotine delivery systems (ENDS) (16.2%), nicotine replacement therapy (NRT) (16.1%), non-NRT medications (varenicline and bupropion) (17.7%), and a combination of NRT and non-NRT medication (14.8%).[67]
- A 2018 study did not find any evidence that ENDS help adult smokers quit at a higher rate than smokers who did not use these products despite ENDS users being more likely to make a quit attempt. In fact, the authors state that "findings indicate that, at the time of this study, ENDS under "real world" use and conditions may have suppressed or delayed quitting among some adult smokers." Specifically, of the 90% of the smokers using e-cigarettes were still smoking at one-year follow-up. Moreover, the study found that ENDS users quit at a lower rate than non-ENDS users regardless of frequency or duration of ENDS use, device type, quitting as reason for use, or e-liquid flavor.[68]

- A meta-analysis of 38 studies that examined the association between e-cigarette use and smoking cessation among adult smokers found that the odds of quitting were less among smokers using e-cigarettes.[69]

Moreover, there is no evidence that flavors in e-cigarettes play any role in smoking cessation. While there are surveys showing that many adults enjoy using flavored products, and anecdotal reports of smokers who says flavored e-cigarettes helped them quit, there is no evidence that smokers could not quit without non-tobacco flavors. Just because some adults may like flavors, it does not mean flavors are needed to help them quit. There has not been a single randomized controlled trial to assess the impact of flavored vs. non-flavored or tobacco-flavored e-cigarettes on smoking cessation outcomes. A systematic review that examined consumer preference for various e-cigarette attributes found "inconclusive evidence" as to whether flavored e-cigarettes assisted quitting smoking."[70]

E-cigarette companies may claim that adult smokers are their target audience, but that is not who is using the product. E-cigarettes have become increasingly popular among youth and young adults, while there has been no significant uptake among older adults. In 2019, 4.5% of adults used e-cigarettes, compared to 3.2% in 2018, 2.8% in 2017, 3.2% in 2016 and 3.5% in 2015 – adult e-cigarette use has remained essentially stable at 3-4 over the past several years. Similarly, adult cigarette use has remained stable during this time as well, hovering around 14%. This lends further evidence that e-cigarettes have not accelerated adult smoking cessation.[71] (See graph below)



When it comes to adults, a significant number of e-cigarette users use both e-cigarettes and cigarettes: in 2019, 36.9% of adult e-cigarette users were also current cigarette smokers (dual users).[72] Little data are available to show what happens with dual users over time. Analysis of FDA's Population Assessment of Tobacco and Health (PATH) data found that nearly 9 out of 10 early dual users were still smoking cigarettes at follow-up.[73] CDC has highlighted the importance of quitting cigarettes completely, not just cutting down. According to the CDC, "If you only cut down the number of cigarettes you smoke by adding another tobacco product, like e-cigarettes, you still face serious health risks. Smokers must quit smoking completely to fully protect their health – even a few cigarettes a day are dangerous."[74] A study using 2013-2014 PATH data found that dual users had toxicant exposures that were similar to those who only used cigarettes.[75]

Limiting Sale of Flavored E-Cigarettes to Adult-Only Retailers Will Not Protect Kids

Limiting sales of flavored tobacco products to certain types of stores is insufficient. The FDA has even noted that, "we are not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use ENDS [e-cigarettes]."[76]

Some youth buy the e-cigarettes they use, either directly from retailers or other kids, or by giving money to others to buy for them. Others get their cigarettes for free from social sources (usually other kids). According to the 2021 Monitoring the Future Survey, over half (54.6%) of 10th grade students say it would be easy to get vaping devices.[77]

There is no evidence that "adult-only tobacco retailers" are more effective at preventing sales to minors. While many vape shops claim to be adult-only, the evidence shows that they are a major source of youth access to e-cigarettes. According to the 2021 National Youth Tobacco Survey (NYTS), 22.2% of youth e-cigarette users report obtaining e-cigarettes from a vape shop or tobacco shop in the past month and 17.7% from a gas station or convenience store.[78] A study in *JAMA Pediatrics* found that in California, e-cigarette sales to minors violations are significantly higher in tobacco and vape shops than any other type of retailer, with 44.7% selling to underage buyers.[79]

FDA Has Failed To Use Its Regulatory Authority Over E-Cigarettes to Protect Kids

Although Congress gave FDA broad regulatory authority over tobacco products in the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), the agency has largely failed to use that authority to regulate e-cigarettes.[80] Despite the requirement in the Tobacco Control Act that new tobacco products (i.e. those introduced after February 15, 2007) obtain an FDA order authorizing their marketing,[81] the FDA has only reviewed a small fraction of the market thus far and of the many marketing denial orders the agency has issued, many companies have filed lawsuits to halt the order or have found ways to circumvent the order. Thus, it is essential for Connecticut and other states to utilize their authority to protect the health of its residents and especially its youth. Moreover, the Tobacco Control Act expressly preserves the power of states to regulate, and even prohibit, the sale of tobacco products.[82]

E-cigarettes were entirely unregulated by FDA until the 2016 issuance of a final rule "deeming" e-cigarettes and other previously unregulated tobacco products subject to FDA regulation.[83] Even after the Deeming Rule was issued, FDA's regulatory power has been severely underutilized. For example, although FDA now has the authority to regulate the methods used in manufacturing, design and testing of vapor products and to mandate new product standards regarding the construction, composition, ingredients and characteristics of vapor products,[84] the agency has issued no regulations requiring good manufacturing practices for e-cigarettes, nor has it issued a single product standard for e-cigarettes. In addition, although e-cigarette manufacturers are under an obligation to provide FDA all documents in their possession relating to the "health, toxicological, behavioral, or physiologic effects" of their products,[85] FDA is enforcing that mandate only as to documents generated by companies before December 31, 2009.[86] This means that virtually no such health documents have been provided for e-cigarettes, most of which were not even on the market until after 2009.

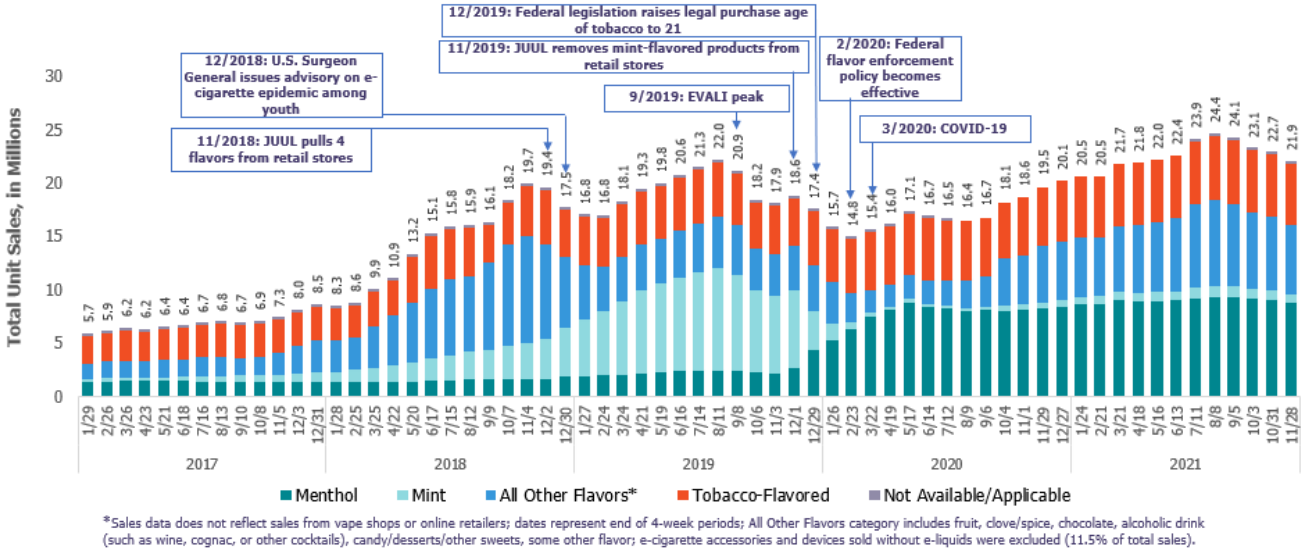
Most significantly as to e-cigarettes, FDA has failed to implement the required premarket review of "new tobacco products" (i.e. products marketed after February 15, 2007), in which manufacturers generally would be required to demonstrate that their products are "appropriate for the protection of public health" in order to stay on the market or enter the market.[87] At the time it issued the Deeming Rule in August 2016, FDA exercised its enforcement discretion to e-cigarettes already on the market, to give their manufacturers a two-year period, until August 2018, to file applications for premarket review.[88] Then, in an August 2017 Guidance, FDA announced it would further defer enforcement of the premarket review requirements for e-cigarettes four additional years until 2022. Thus, FDA would allow thousands of flavored e-cigarettes to remain on the market without having to even submit applications demonstrating that they met the public health standard in the statute.
As the result of a lawsuit brought against FDA by several public health groups, a federal court established a deadline of September 2020 for industry marketing applications and a one-year deadline for completion of FDA review.[89] While this one-year review period has now passed, the FDA has yet to issue decisions on e-cigarette products that have the largest market shares or are most popular with kids, such as Juul, Vuse Alto, NJOY, blu, Smok and Suorin. The FDA also is still considering whether to authorize the sale of any menthol-flavored e-cigarettes. In addition, the agency has indicated that it will not prioritize enforcement against the products that remain on the market pending decisions on their applications, meaning that these products can continue to be sold for an indefinite period. Meanwhile, more than 40 companies have filed lawsuits challenging their marketing denial orders and many have found ways to circumvent the FDA's authority.[90]

FDA's actions have demonstrated that a piecemeal approach to regulating flavored e-cigarettes will not reverse the youth epidemic. In February 2020, the Agency instituted an enforcement policy prohibiting flavors other than tobacco and menthol in cartridge-based products (like Juul), but left thousands of kid-friendly e-cigarettes on the market, including flavored disposable e-cigarettes, flavored e-liquids that can be used in refillable devices, and menthol pod-based products.

Sales and youth use data show that the FDA missed the opportunity to make far greater progress in reducing youth e-cigarette use as kids quickly migrated to the flavored products that were exempt from the policy:

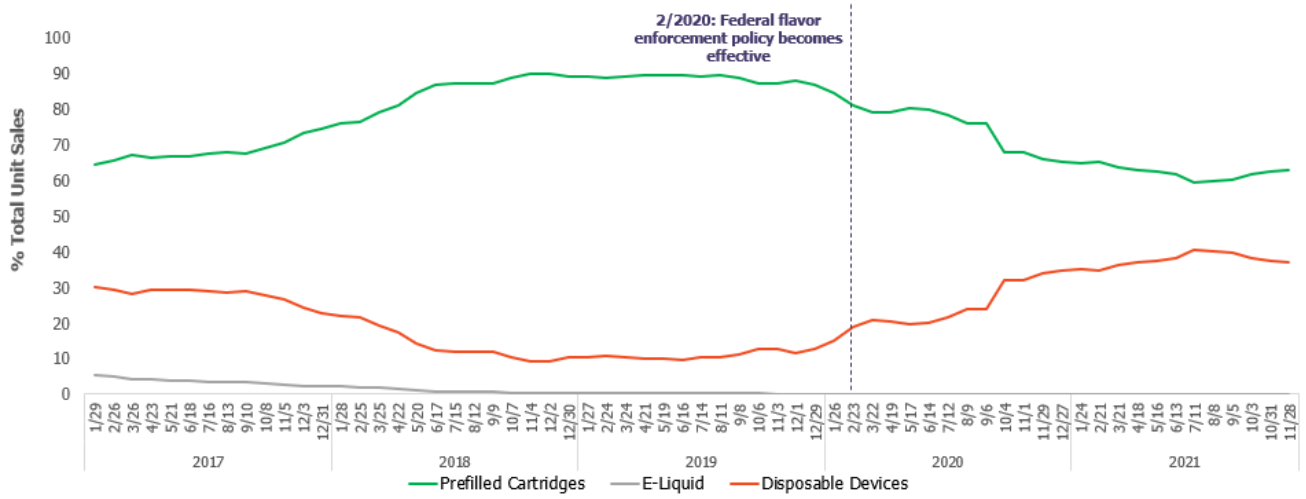
- In 2021, 55.8% of high school e-cigarette users reported using disposable e-cigarettes, and Puff Bar, a disposable e-cigarette was reported as the most popular e-cigarette device among youth. Among current youth users of disposable e-cigarettes, the most commonly used flavor type is fruit (78.7%), followed by candy/desserts/other sweets (32.3%).[91]
- From February 2020 to November 28, 2021, sales of disposable e-cigarettes increased by 190.7% (from 2.8 million units to 8.1 million units). During this period, the market share of disposable devices increased from 18.8% to 36.9% of total e-cigarette sales (see chart below). Flavors other than tobacco, mint and menthol comprise 80% of disposable e-cigarette sales.[92]
- Among high school users of flavored e-cigarettes, 30% reported using menthol products, including 46% of users of flavored cartridge-based products like Juul.[93]
- From February 2020 to November 28, 2021, overall menthol flavored e-cigarette sales increased by 38.3% (from 6.4 million to 8.8 million units), including a 44.4% increase in menthol-flavored cartridge sales (from 5.9 million units to 8.5 million units). See chart below. As of November 28, 2021, menthol flavored e-cigarettes sales accounted for 40.2% of the overall e-cigarette market and 61.6% of the prefilled cartridge market.[94]
- In 2020, 80% of 10th and 12th grade e-cigarette users reported that they could still easily obtain nicotine solutions in flavors other than tobacco or menthol.[95]

National E-Cigarette Unit Sales by Flavor, 4 Week Estimates 1/2017 – 11/2021*



*Sales data does not reflect sales from vape shops or online retailers; dates represent end of 4-week periods; All Other Flavors category includes fruit, clove/spice, chocolate, alcoholic drink (such as wine, cognac, or other cocktails), candy/desserts/other sweets, some other flavor; e-cigarette accessories and devices sold without e-liquids were excluded (11.5% of total sales).

National E-Cigarette Unit Sales by Product Type, 4 Week Estimates 1/2017 – 11/2021*



*Sales data does not reflect sales from vape shops or online retailers; dates represent end of 4-week periods; prefilled cartridges include tanks, cartridges, and pods used in rechargeable and reusable e-cigarette device; disposable devices include nonrechargeable and nonreusable e-cigarette devices that are not intended to be refilled with e-liquid after being depleted; e-liquids are containers of the liquid used in e-cigarette devices, which typically contains a humectant (e.g., propylene glycol), nicotine, and flavoring.

That the industry—and America's kids—have taken advantage of these loopholes is well-established. A May 2020 industry analyst report noted, "We expect brands in the disposable e-cig segment to continue to gain market share as long as they are not covered by the FDA's restriction on non-tobacco/non-menthol flavor variants."[96] According to a January 2020 article in *The New York Times*, "Teens Find a Big Loophole in the New Flavored Vaping Ban," many youth report Puff Bar and other disposable products as their product of choice.[97]

The evidence demonstrate how quickly kids will shift to whatever flavored e-cigarettes are left on the market. Once certain flavored products were removed from the market, kids quickly migrated to the flavored products that were still available. This makes clear the need for states to avoid exemptions for particular flavored products or "narrow approaches" favored by the industry. All flavored tobacco products are designed to hook kids, and leaving some products on the market only lets kids know which products they should try (and determines the next popular flavored tobacco product for kids). Rather than playing whack-a-mole with a handful of egregious products only after they become popular with our nation's kids, states should clear the market of all flavored e-cigarettes and tobacco products.

The FDA stood by for more than a decade while Big Tobacco hooked a generation of kids on e-cigarettes. The FDA's February 2020 guidance and premarket review process have prioritized the e-cigarette industry over the health of America's kids, falling far short of clearing the market of flavored e-cigarettes. Data and experience show that the progress to date is fragile and can quickly be reversed. Urgent action is needed to eliminate all flavored e-cigarettes, including the menthol products and cheap disposable e-cigarettes to which kids have rapidly migrated. Connecticut's kids can't wait for FDA to act.

Connecticut Should Address Youth Tobacco Addiction and Tobacco-related Health Disparities by Banning the Sale of All Flavored Tobacco Products, In Addition to E-Cigarettes

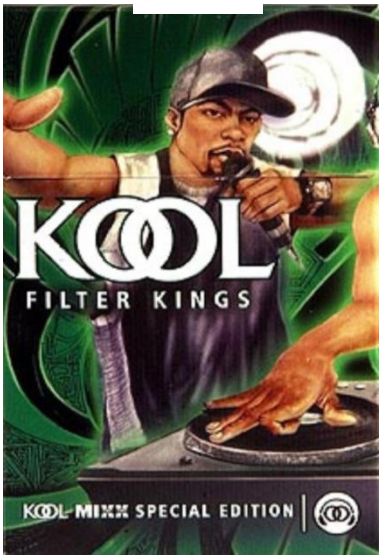
While the epidemic of youth e-cigarette use threatens to undue all of the progress Connecticut has made in reducing tobacco use and must be addressed immediately, equally urgent action is needed to address a public health crisis that has gotten less attention, but over the years has done even greater harm: the marketing and sale of all other flavored tobacco products, especially menthol cigarettes and flavored cigars. These products are marketed just as insidiously to youth and communities of color, the result of which has been a tremendous loss of life. Banning the sale of <u>all</u> flavored tobacco products is one of the most important things you can do to protect the health of Connecticut's kids, reverse health disparities in the State, and prevent the 4,900 deaths in Connecticut each year that are due to tobacco use.[98]

Tobacco companies have long known that menthol cigarettes reduce the harshness of their products and make them easier to use by new users, almost all of whom are under age 18.[99] Menthol imparts a cooling and soothing sensation, masking the harshness of tobacco and making it easier for beginner smokers and kids to tolerate smoking. The FDA's Tobacco Products Scientific Advisory Committee (TPSAC) concluded that menthol cigarettes increase the number of children who experiment with cigarettes and the number of children who become regular smokers, increasing overall youth smoking. Further, they found that people who initiate smoking using menthol cigarettes are more likely to become addicted and become long-term daily smokers.[100]

1966

1984

2004



Images courtesy of Stanford Research Into the Impact of Advertising (SRITA) and TrinketsandTrash.Org.

The continued availability of menthol cigarettes threatens the progress Connecticut has made in reducing adult smoking, particularly among Black Americans. Prevalence of menthol use is highest among Black smokers – 85% of all Black smokers smoke menthol cigarettes, compared to 29% of Whites. [101] This disparity in use is the direct result of the conscious decisions of the major tobacco companies. Dating back to the 1950s, the tobacco industry has targeted Black communities with marketing for menthol cigarettes through sponsorship of community and music events, targeted magazine advertising, youthful imagery, and marketing in the retail environment.[102] This targeting continues today: magazine advertisements continue to target Black Americans and menthol cigarettes continue to be heavily advertised, widely available, and priced cheaper in certain Black communities, making them more appealing, particularly to price-sensitive youth. [103] Nationally, Newport cigarettes (the most popular menthol brand among Black smokers) are significantly less expensive in neighborhoods with higher proportions of Black Americans.[104] A wealth of research indicates that Black neighborhoods have a disproportionate number of tobacco retailers, more price discounts for tobacco products, pervasive tobacco marketing, and in particular, more marketing of menthol products.[105]

Both TPSAC's and FDA's own scientific analyses conclude that menthol cigarettes are associated with increased nicotine dependence and reduced success in smoking cessation.[106] The difficulty that Black Americans experience in quitting smoking, and consequently their higher rates of tobacco-related disease and death are due, in part, to their greater use of menthol cigarettes.[107] While research shows that Black smokers are highly motivated to quit smoking and are more likely than White smokers to have made a quit attempt and used counseling services in the previous year, they are less likely than White smokers to successfully quit smoking.[108] As a result, tobacco use is a major contributor to three of the leading causes of death among Black Americans - heart disease, cancer and stroke – and Black Americans die

from these diseases at higher rates than other communities.[109] Researchers estimate that, among the Black community, menthol cigarettes were responsible for 1.5 million extra smokers, 157,000 smoking-related premature deaths and 1.5 million excess life-years lost during 1980-2018. During this time, Black Americans represented 15% of extra new smokers, 41% of excess premature deaths and 50% of excess life-years lost, despite only accounting for 12% of the population.[110]

In addition to the documented disparity in menthol cigarette use among Black Americans, new research shows that use of menthol cigarettes is also disproportionately high among Hispanic smokers, lesbian, gay, and bisexual smokers, smokers with mental health problems, socioeconomically disadvantaged populations, and pregnant women.[111]

In recent years, cigars have surpassed cigarettes in popularity among young people, and they are disproportionately used by Black youth.[112] In Connecticut, 5.7% of high school boys are current cigar smokers.[113] A primary reason for the popularity of cigars among youth is the wide array of available flavors. In fact, 73.8% of youth cigar smokers smoked cigars "because they come in flavors I like."[114] Flavored cigars have proliferated in recent years and now make up more than half the U.S. cigar market. The share of flavored cigars sold in convenience stores rose from 45% in 2009 to 53.3% in 2020. Among flavored cigars sold in these stores in 2020, the most popular flavors were sweet or candy (30.6%), fruit (29.5%), concept (21.4%), and wine (9.0%).[115] There are over 250 cigar flavors, including of Cherry Dynamite, Brownie, and Strawberry Kiwi.[116] Cheap, sweet cigars can serve as an entry product for kids to a lifetime of smoking. Similar to e-cigarettes, cigars are marketed using social media, hip hop and rap music event sponsorship, celebrity endorsements and point-of-sale promotions.[117]

Prohibiting the sale of menthol cigarettes, flavored cigars and all other flavored tobacco products is an essential step toward protecting our children and our community from the tobacco industry's aggressive efforts to hook children to these dangerous, addictive products.

State and Local Action to Restrict the Sale of Flavored Tobacco Products

In recognition of the health harms caused by flavored tobacco, a growing group of states and communities has taken action to prohibit the sale of flavored tobacco. States and localities can

implement additional sales restrictions on menthol cigarettes and flavored non-cigarette tobacco products. Despite inevitable opposition from tobacco companies, states and localities have clear authority to restrict the sale of flavored tobacco products (or any tobacco product) to reduce tobacco use and its harms to its citizens.

In November 2019, Massachusetts became the first state to restrict the sale of all flavored tobacco products, including menthol cigarettes. The policy went into effect June 1, 2020. Massachusetts was soon followed by prohibitions on the sale of flavored e-cigarettes in New Jersey, New York and Rhode Island, and most recently, California enacted a prohibition on the sale of most flavored tobacco products, including menthol cigarettes (implementation of California's law is pending due to a referendum challenge by the tobacco industry). These five states are joined by a growing list of over 335 localities around the country restrict sales of flavored tobacco products, and over 100 of these include menthol cigarettes in their sales restriction, with more cities and states slated to act this year.[118] I urge you to join them. Connecticut needs to be a leader on this issue and pass this legislation without delay.

Conclusion

We are facing an epidemic in youth e-cigarette use. Parents, school officials, and health care providers from across the country have recognized that a new generation of young people are becoming addicted to nicotine with potentially devastating long term consequences. Meanwhile, the ongoing devastation caused by the use of menthol flavoring in cigarettes continues to addict kids and disproportionately impact Black communities in Connecticut.

Whereas the potential public health benefit of flavored e-cigarettes is entirely speculative, the crisis of youth usage is real and growing. The scientific evidence leaves no doubt that flavored e-cigarettes, just like menthol-flavored cigarettes and the other flavored tobacco products that remain on the market, increase the number of people who initiate tobacco use and become addicted, particularly kids. We strongly encourage the Joint Committee on Public Health and the Connecticut Legislature to prohibit the sale of all flavored electronic delivery systems and products that have a nicotine content higher than 35 milligrams per milliliter as proposed in SB 367 to curtail the youth e-cigarette epidemic and ensure that these flavored tobacco products can no longer continue to addict our youth. Connecticut's kids deserve every protection available from the insidious products and predatory marketing of the tobacco industry.

Thank you for the opportunity to submit comments on this important issue.

[1] Hsu, G, et al., "Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites," Journal of Medical Internet Research, 20(3), published online March 12, 2018.
[2] Gentzke, A, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021," MMWR 71(5): 1-29, March 10, 2022, https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf.
[3] See Table 2-8 in Institute of Medicine, *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products*, Washington, DC: The National Academies Press, 2015, http://iom.nationalacademies.org/Reports/2015/TobaccoMinimumAgeReport.aspx
[4] Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.
[5] Hsu, G, et al., "Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites," Journal of Medical Internet Research, 20(3), published online March 12, 2018.
[6] Office of the Surgeon General, "Surgeon General's Advisory on E-Cigarette Use Among Youth," December 18, 2018, https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf.
[7] University of Michigan, *Monitoring the Future Study*, 2018. http://monitoringthefuture.org/data/18data/18drtbl3.pdf
[8] CDC, 2019 Youth Risk Behavior Survey, Available at http://nccd.cdc.gov/youthonline/.
[9] Park-Lee, E, et al., "E-Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, 2021," *MMWR*, 70(39): 1387-1389, October 1, 2021, https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf.
[10] Hammond D, et al., "Indicators of dependence and efforts to quit vaping and smoking among youth in Canada, England and the USA," *Tobacco* Control, published online January 31, 2021.
[11] Hammond, D, et al., "Trends in e-cigarette brands, devices and the nicotine profile of products used by youth in England, Canada and the USA: 2017-2019," *Tobacco Control*, published online June 7, 2021.
[12]Jan Hoffman, "The Price of Cool: A Teenager, a Juul and Nicotine Addiction," November 16, 2018 The New York Times, https://www.nytimes.com/2018/11/16/health/vaping-juul-teens-addiction-nicotine.html
[13] Zhu, S-H, et al., "Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites," Journal of Medical Internet Research, 20(3), published online March 12, 2018.
[14] HHS, Office of the Surgeon General, "Smoking Cessation: A Report of the Surgeon General," 2020 https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf.
[15] HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
[16] FDA, Technical Project Lead (TPL) Review of PMTAs, September 17, 2021, https://www.fda.gov/media/152504/download.
[17] Park-Lee, E, et al., "E-Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, 2021," *MMWR*, 70(39): 1387-1389, October 1, 2021, https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf.
[18] FDA, "Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance," March 13, 2019, https://www.fda.gov/media/121384/download.
[19] Park-Lee, E, et al., "E-Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, 2021," *MMWR*, 70(39): 1387-1389, October 1, 2021, https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf.
[20] Wang, TW, et al., "E-cigarette Use Among Middle and High School Students – United States, 2020," MMWR, Volume 69, September 9, 2020, https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf.
[21] HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
[22] Gentzke, A, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021," MMWR 71(5): 1-29, March 10, 2022, https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf.
[23] CDC, Office of the Surgeon General, "Health Care Professionals: Educate Your Young Patients About the Risks of E-cigarettes," https://e-cigarettes.surgeongeneral.gov/documents/SGR_E-Cig_Health_Care_Provider_Card_508.pdf
[24] US Department of Health and Human Services (HHS), *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
[25] CDC, Office of the Surgeon General, "Know the Risks: E-Cigarettes and Young People, Frequently Asked Questions," https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_ECig_FAQ_508.pdf
[26] Pax Labs, Inc. (former name of Juul Labs), *Pax Labs, Inc. Granted U.S. Patent for Nicotine Salt E-Cigarette*, December 22, 2015, https://www.juulvapor.com/media/wysiwyg/Juul/Juul_USPTO_Patent_Press_Release_15-1216.pdf.
[27] Office of the Surgeon General, "Surgeon General's Advisory on E-Cigarette Use Among Youth," December 18, 2018, https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf.
[28] Jackler, RK, Ramamurthi, D, *Nicotine arms race: Juul and the high-nicotine product market*, *Tobacco Control*, published online February 6, 2019.
[29] Jackler, RK, Ramamurthi, D, "Nicotine arms race: Juul and the high-nicotine product market" *Tobacco Control*, published online February 6, 2019.
[30] Gentzke, A, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021," MMWR 71(5): 1-29, March 10, 2022, https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf.
[31] Kong, G, et al., "Appeal of JUUL among adolescents," *Drug & Alcohol Dependence,* published online October 28, 2019.

[32] Jackler, RK, Ramamurthi, D, "Nicotine arms race: Juul and the high-nicotine product market" *Tobacco Control*, published online February 6, 2019.
[33] Romberg, AR, et al., "Patterns of nicotine concentrations in electronic cigarettes sold in the United States, 2013-2018," *Drug and Alcohol Dependence*, published online August 5, 2018.
[34] HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016. See also, Leventhal, AM, et al., "Association of Electronic Cigarette Use With Initiation of Combustible Tobacco Product Smoking in Early Adolescence," *Journal of the American Medicine Association*, 314(7): 700-707, 2015. Wills, Thomas A, et al., "Longitudinal study of e-cigarette use and onset of cigarette smoking among high school students in Hawaii," Tobacco Control, published online first January 25, 2016. Wills, TA, et al., "E-cigarette use is differentially related to smoking onset among lower risk adolescents," *Tobacco Control*, published online August 19, 2016. Barrington-Trimis, JL, et al., "E-Cigarettes and Future Cigarette Use," *Pediatrics*, 138(1), published online July 2016.
[34] Barrington-Trimis, JL, et al., "E-Cigarettes and Future Cigarette Use," *Pediatrics*, 138(1), published online July 2016. Wills, TA, et al., "E-cigarette use is differentially related to smoking onset among lower risk adolescents," *Tobacco Control*, published online August 19, 2016.
[35] National Academies of Sciences, Engineering, and Medicine. 2018. *Public health consequences of e-cigarettes*. Washington, DC: The National Academies Press. http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx .
[36] Berry, KM, et al., "Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths," *JAMA Network Open*, 2(2), published online February 1, 2019.
[37] WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.
[38] Yoong, SL, et al., "Associations between electronic nicotine delivery systems and electronic non-nicotine delivery systems with initiation of tobacco use in individuals aged <20 years. A systematic review and meta-analysis," *PLoS ONE 16(9): e0256044.*
[3939] Barrington-Trimis, JL, et al., "E-Cigarettes and Future Cigarette Use," *Pediatrics*, 138(1), published online July 2016. Wills, TA, et al., "E-cigarette use is differentially related to smoking onset among lower risk adolescents," *Tobacco Control*, published online August 19, 2016.
[40] FDA, Technical Project Lead (TPL) Review of PMTAs, September 17, 2021, https://www.fda.gov/media/152504/download.
[41] Cheng, T, *Chemical Evaluation of Electronic Cigarettes*, *Tobacco Control* 23:ii11-ii17, May 2014, http://tobaccocontrol.bmj.com/content/23/suppl_2/ii11.full. Goniewicz, ML, et al., *Levels of selected carcinogens and toxicants in vapour from electronic cigarettes*, *Tobacco Control* 23(2):133-9, March 6, 2013. Williams, M, et al., *Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol*, *PlosOne,* 8(3), March 2013. See also Williams, M, *Electronic Cigarette Liquids and Vapors: Is It Harmless Water Vapor*, presented October 3, 2013 at TRDRP Electronic Cigarette Webinar, http://www.trdrp.org/docs/Williams%20ecig%20vapor%20this%20time%20slides%202013.pdf. NASEM, *Public Health Consequences of E-Cigarettes*, 2018.
[42] National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-Cigarettes*, Washington, DC: The National Academies Press, 2018, http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx.
[43] HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
[44] Barrington-Trimis, JL, Samet, JM, & McConnell, R, *Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?*, The Journal of the American Medical Association, doi:10.1001/jama.2014.14830, published online November 10, 2014.
[45] Gottlieb, S and Abernethy, A. *Understanding the Health Impact and Dangers of Smoke and 'Vapor'.* FDA Voices: Perspectives from FDA Leadership and Experts. https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/understanding-health-impact-and-dangers-smoke-and-vapor.
[46] 944 F.3d 266, 271 (D.C. Cir. 2019).
[47] *Id.* at 274 (internal citations omitted).
[48] See discussion on pg. 12-13 of this written comment.
[49] HHS, Office of the Surgeon General, *Smoking Cessation: A Report of the Surgeon General*, 2020 https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf.
[50] WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Geneva: World Health Organization; 2021. https://www.who.int/publications/i/item/9789240032095
[51] HHS. Smoking Cessation. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.
[52] NASEM, *Public Health Consequences of E-Cigarettes*, 2018.
[53] Gotts, JE, et al., "What are the respiratory effects of e-cigarettes?" *British Medical Journal* 366:l5275, 2019, https://www.bmj.com/content/bmj/366/bmj.l5275.full.pdf.
[54] Traboulsi, Hussein et al. "Inhalation Toxicology of Vaping Products and Implications for Pulmonary Health." *International journal of molecular sciences* vol. 21,10 3495. 15 May 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7278963/
[55] Gotts, J. et al., "What are the respiratory effects of e-cigarettes?" The BMJ, 366:l5275, published online September 30, 2019. https://www.bmj.com/content/bmj/366/bmj.l5275.full.pdf
[56] *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products* (Final Rule), 81 Fed. Reg. at 29029-30 (May 10, 2016).

[57] Eissenberg, T., et al., "Invalidity of an Oft-Cited Estimate of the Relative Harms of Electronic Cigarettes," AJPH, published online January 8, 2020, https://ajph.aphapublications.org/doi/10.2105/AJPH.2019.305424.
[58] Editorial, *E-cigarettes: Public Health England's evidence-based confusion*, *The Lancet*, vol. 386, at 829 (Aug. 29, 2015).
[59] NASEM, *Public health consequences of e-cigarettes*, 2018, Washington, DC: The National Academies Press.
[60] HHS, Office of the Surgeon General, "Smoking Cessation: A Report of the Surgeon General," 2020 https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf.
[61] U.S. Preventive Services Task Force, *Final Recommendation Statement: Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions*, May 2019, https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1;
[62] National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-Cigarettes*, Washington, DC: The National Academies Press, 2018, http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx;
[63] King, BA, et al., "Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011," *Nicotine & Tobacco Research*, 15(9):1623-7, 2013. See also, King, BA, et al., "Trends in Awareness and Use of Electronic Cigarettes among U.S. Adults, 2010-2013," *Nicotine & Tobacco Research*, first published online September 19, 2014 and Fiore, MC, et al., Treating Tobacco Use and Dependence: 2008 Update, U.S. Public Health Service Clinical Practice Guideline, May 2008, http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.
[64] WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.
[65] American Academy of Pediatrics et al., v. U.S. Food & Drug Administration, et al. Government's Opposition to the Motions for Stay Pending Appeal and Consent to the motion to Expedite Review, December 31, 2019.
[66] Chen R, et al. Effectiveness of e-cigarettes as aids for smoking cessation: evidence from the PATH Study cohort, 2017–2019. Tobacco Control. 2022 Jan 11.
[67] Kaplan B, Galiatsatos P, Breland A, Eissenberg T, Cohen JE. Effectiveness of ENDS, NRT and medication for smoking cessation among cigarette-only users: a longitudinal analysis of PATH Study wave 3 (2015–2016) and 4 (2016–2017), adult data. Tobacco Control. 2021 Sep 14.
[68] Weaver, Scott R., et al., "Are electronic nicotine delivery systems helping cigarette smokers quit? Evidence from a prospective cohort study US adult smokers, 2015-2016," *PLoS One* 13(7), July 9, 2018.
[69] Kalkhoran, S & Glantz, SA, "E-cigarettes and smoking cessation n real-world and clinical settings: a systematic review and meta-analysis," *Lancet Respiratory Medicine* 4(2):116-28, 2016.
[70] Zare, S, et al., "A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type," PLoS One. 2018 Mar 15;13(3), 2018.
[71] Cornelius, ME, "Tobacco Product Use Among Adults — United States, 2019," *MMWR* 69(46):1736-1742, November 20, 2020, https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6946a4-H.pdf. Dai, H & Levanthal, A.M, "Prevalence of e-Cigarette Use Among Adults in the United States, 2014-2018," *JAMA,* September 16, 2019, https://jamanetwork.com/journals/jama/fullarticle/2751687?guestAccessKey=f449ac04-5797-4d99-9b05-39234c35f47e&utm_source=silverchair&utm_medium=email&utm_campaign=article_alert-jama&utm_content=olf&utm_term=091619
[72] Cornelius, ME, "Tobacco Product Use Among Adults — United States, 2019," *MMWR* 69(46):1736-1742, November 20, 2020, https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6946a4-H.pdf.
[73] Coleman, B., et al., "Transitions in electronic cigarette us among adults in the Population Assessment of Tobacco and Health (PATH) Study, Waves 1 and 2 (2013-2015)," *Tobacco Control*, published online April 25, 2018.
[74] CDC, "Powerful new Tips from Former Smokers" ads focus on living with vision loss and colorectal cancer," CDC Press Release, March 26, 2015, http://www.cdc.gov/media/releases/2015/p0326-tips.html. See also: CDC, "Dual Use of Tobacco Products." http://www.cdc.gov/tobacco/campaign/tips/diseases/dual-tobacco-use.html#ten.
[75] Goniewicz, ML, et al., "Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes," *JAMA Network Open* 1(8):e185937. doi:10.1001/jamanetworkopen.2018.5937, 2018.
[76] FDA, Technical Project Lead (TPL) Review of PMTAs, September 17, 2021, https://www.fda.gov/media/152504/download.
[77] University of Michigan, 2021 Monitoring the Future Study, *Trends in Availability of Drugs as Perceived by 10th Graders,* http://monitoringthefuture.org/data/21data/table16.pdf.
[78] Gentzke, A, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021," MMWR 71(5): 1-29, March 10, 2022, https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf.
[79] Roeseler, A, et al., "Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops," *JAMA Pediatrics*, published online June 24, 2019.
[80] Pub. L. No. 111-31, 123 Stat. 1776 (2009)(codified at 21 U.S.C. §§ 387-387u).
[81] 21 U.S.C §387j.
[82] 21 U.S.C. §387p.
[83] *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 (May 10, 2016) ("Deeming Rule").
[84] 21 U.S.C § 387(f)(e), 387(g).
[85] 21 U.S.C. § 387(d)(a)(4).
[86] FDA, Guidance for Industry, "Health Document Submission Requirements for Tobacco Products (Revised) (October, 2017), at 14. (August 2017 Guidance), at 8.
[87] 21 U.S.C. § 387(j).

[88] 81 Fed. Re. 28.978.
[89] *See Am. Acad. of Peds. et. al. v. FDA*, 399 F.Supp.3d 479 (D. Md. 2019).
[90] Campaign for Tobacco-Free Kids, *An E-Cigarette Market Update: Flavored Products Remain Widely Available Three Months After Court-Ordered Deadline for FDA to Rule on Marketing Applications*, December 2021, https://www.tobaccofreekids.org/assets/content/press_office/2021/ecigreport.pdf.
[91] Wang, TW, et al., "E-cigarette Use Among Middle and High School Students – United States, 2020," MMWR, Volume 69, September 9, 2020, https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf.
[92] CDC Foundation & Information Resources, Inc., "Monitoring U.S. E-Cigarette Sales: National Trends," https://www.cdcfoundation.org/programs/monitoring-e-cigarette-use-among-youth. Data from Information Resources, Inc. (IRI), which includes e-cigarette sales data from convenience stores, gas stations and other retail store chains. Sales from the internet and tobacco-specialty stores, including vape shops, are not included.
[93] Park-Lee, E, et al., "E-Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, 2021," *MMWR*, 70(39): 1387-1389, October 1, 2021, https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039a4-H.pdf.
[94] CDC Foundation & Information Resources, Inc., "Monitoring U.S. E-Cigarette Sales: National Trends," https://www.cdcfoundation.org/programs/monitoring-e-cigarette-use-among-youth. Data from Information Resources, Inc. (IRI), which includes e-cigarette sales data from convenience stores, gas stations and other retail store chains. Sales from the internet and tobacco-specialty stores, including vape shops, are not included.
[95] Miech, R, et al., "Trends in Use and Perceptions of Nicotine Vaping Among US Youth from 2017 to 2020," *JAMA Pediatrics*, published online December 15, 2020.
[96] Goldman Sachs, "Americas Tobacco: Nielsen Data Through 5/16 - Cig Consumption Increases as Cig Vol Declines Continue to Moderate," May 26, 2020.
[97] Kaplan, S, "Teens Find a Big Loophole in the New Flavored Vaping Ban," *The New York Times,* January 31, 2020 https://www.nytimes.com/2020/01/31/health/vaping-flavors-disposable.html.
[98] CDC, *Best Practices for Comprehensive Tobacco Control Programs—2014,* http://www.cdc.gov/tobacco/stateandcommunity/best_practices/.
[99] HHS, *Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012, http://www.cdc.gov/Features/YouthTobaccoUse/.
[100] TPSAC, FDA, "Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, 2011, https://wayback.archive-it.org/7993/20170405201731/https:/www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf.
[101] Villanti, A., et al., "Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014," *Tobacco Control*, published online October 20, 2016
[102] Yerger, VB, et al., "Racialized geography, corporate activity, and health disparities: Tobacco industry targeting of inner cities," *Journal of Health Care for the Poor and Underserved*, 18: 10-38, 2007. See also RJ Reynolds. Black Street Scenes: review and recommendations. Winston-Salem, NC: R.J. Reynolds Tobacco Company, 1983. Available at http://legacy.library.ucsf.edu/tid/onb19d00.
[103] Rodriguez, D, et al., "Predictors of tobacco outlet density nationwide: a geographic analysis," *Tobacco Control* 22(5):349-55, 2013. See also Lee, JG, et al., "Inequalities in tobacco outlet density by race, ethnicity and socioeconomic status, 2012, USA: results from the ASPIRE Study," *Journal of Epidemiology and Community Health* 71(5):487-492, 2017. Henriksen, L, et al., "Targeted Advertising, Promotion, and Price for Menthol Cigarettes in California High School Neighborhoods," *Nicotine & Tobacco Research* 14(1):116-21, 2012.
[104] Resnick, EA, et al., *Cigarette Pricing Differs by U.S. Neighborhoods—A BTG Research Brief.* Chicago, IL: Bridging the Gap Program, Health Policy Center, Institute for Health Resarch and Policy, University of Illinois at Chicago, 2012, www.bridgingthegapresearch.org.
[105] Moreland-Russell, S, et al., "Disparities and Menthol Marketing: Additional Evidence in Support of Point of Sale Policies," *International Journal of Environmental Research and Public Health*, 10: 4571-4583, 2013. Schleicher, N, et al., "Tobacco Marketing in California's Retail Environment (2008-2011), Final report for the California Tobacco Advertising Survey. Stanford, CA: Stanford Prevention Research Center, July 2013. Henriksen, L., et al., "Targeted Advertising, Promotion, and Price for Menthol Cigarettes in California High School Neighborhoods," Nicotine & Tobacco Research, June 24, 2011. Seidenberg, AB, "Cigarette Advertising Differs by Community Demographic Profile," *American Journal of Health Promotion* 24(6):e26-e31, July/August 2010.
[106] TPSAC, Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, July 21, 2011 http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf
[107] FDA, "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes," http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/UCM361598.pdf, 2013; Tobacco Products Scientific Advisory Committee, FDA, "Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, 2011, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697;pdf.; Alexander, LA, et al., "Why we must continue to investigate menthol's role in the African American smoking paradox," *Nicotine & Tobacco Research, 18(S1):* S91-S101, 2016;
[108] See e.g., CDC, "Quitting Smoking Among Adults—United States, 2000-2015," *MMWR*, 65(52): 1457-1464, January 6, 2017, https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6552a1.pdf. Royce, J, et al., "Smoking cessation factors among African Americans and Whites: COMMIT Research Group," *American Journal of Public Health* 83(2):220-6, February 1993. https://www.fda.gov/advisoryCommittees/CommitteesMeetingMaterials/tobaccoproductsScientificAdvisoryCommittee/default.htm

[109] HHS, "Tobacco Use Among US Racial/Ethnic Minority Groups—African Americans, American Indians and Alaskan Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General," 1998; CDC, National Vital Statistics Report, Vol. 68, No. 9. Table 10, 2019 https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_09-508.pdf.
[110] Mendez, D and Le, TT, "Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018," *Tobacco Control*, published online September 16, 2021.
[111] Cristine D. Delnevo, et al., "Banning Menthol Cigarettes: A Social Justice Issue Long Overdue," *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.
[112] Gentzke, A, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021," MMWR 71(5): 1-29, March 10, 2022, https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf.
[113] CDC, 2019 Youth Risk Behavior Survey, Available at http://nccd.cdc.gov/youthonline/.
[114] Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.
[115] Delnevo, CD, et al. "Cigar Sales in Convenience Stores in the US, 2009-2020," *JAMA* 326(23):2429-2432.
[116] Delnevo, CD, et al., "Changes in the mass-merchandise cigar market since the Tobacco Control Act," *Tobacco Regulatory Science,* 3(2 Suppl 1): S8-S16, 2017.
[117] Ganz, O, et al., "Swisher Sweets 'Artist Project': using musical events to promote cigars," *Tobacco Control*, published online February 8, 2018.
[118] Campaign for Tobacco-Free Kids, "States & Localities That Have Restricted the Sale of Flavored Tobacco Products," https://www.tobaccofreekids.org/assets/factsheets/0398.pdf.